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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,432	08/01/2001	John M. Cuckler	10557/247605	6380
30559	7590	12/09/2005	EXAMINER	
CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			WILLSE, DAVID H	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

88

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/920,432		CUCKLER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Dave Willse		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on August 8, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-38, 41, 42, 47, 49, 51, 53, 56, 57, 59, 61, 63, 66-69, 71, 73, 74 and 76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

Continuation of Disposition of Claims: Claims pending in the application are 1,3-8,10-38,41,42,47,49,51,53,56,57,59,61,63,66-69,71,73,74 and 76.

At the Applicant's request (Response received on August 8, 2005), the Notice of Non-Compliant Amendment of July 8, 2005, is hereby vacated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 10-38, 41, 42, 47, 49, 51, 53, 56, 57, 59, 61, 63, 66-69, 71, 73, 74, and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In claim 1, lines 22-23 imply that a second concave surface extends distally to a lesser extent "at other positions around the rim of the cup", whereas the buttress as originally disclosed extends only a partial distance around the rim of the cup (e.g., column 3, lines 4-5, of US 5,931,870) and the cup wall surface beyond the annular rim **52** appears to be convex rather than concave (Figures 15 and 16; column 4, line 14; etc.); attention is also directed to the grounds of rejection under 35 U.S.C. 112, second paragraph, as set forth below. A similar problem occurs at lines 23-25 of claim 13 and is compounded by the difficulties identified below for said claim. Regarding claim 14, because a rim extends about a *periphery* of the cup *member* or *body* (claim 14, lines 4-5) and because the reverse curve portion **15** appears to define a *convex* distal surface portion (Figures 5 and 7), it is not seen how the original disclosure supports a further (or *any*) "concave surface of the cup body wall extending *distally* to a greater extent adjacent the flange portion" (claim 14, lines 11-12; emphasis added); even the curved buttress **22** does not appear to extend

Art Unit: 3738

distally relative to the flat plane 13A as depicted in Figure 5. Analogous problems are found in claim 23. The observations concerning claim 1 as discussed above are also applicable to claim 35 and others: the rim extending about the *periphery* of the cup body (claim 35, lines 4-5) contradicts with portions *of the cup body* extending distally (or beyond) the rim and thus the periphery of the cup body (claim 35, last three lines). There are inconsistencies as to whether the broadly claimed buttress 65 element is part of the cup body (and hence part of the cup body periphery) or not. For reasons provided above and below, the examiner is unable to ascertain the scope of the present claims in light of the specification, especially since there is no explanation of limitations such as at claim 1, lines 22-23, in the original disclosure; prior art may be applicable once these problems have been resolved. **The Applicant is reminded that 37 CFR 1.173(c) requires that the Applicant supply “an explanation of the support in the disclosure of the patent for the changes made to the claims”.** This requirement will be strictly enforced in subsequent Office actions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 10-38, 41, 42, 47, 49, 51, 53, 56, 57, 59, 61, 63, 66, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether “a concave surface on a distal side of the cup body” (e.g., claim 1, line 4) is the same as or different from “a concave surface of the cup body wall” (e.g., claim 1, line 22). If the latter “concave surface of the cup body wall” corresponds, at least in part, to an inner surface of the buttress 65, then how can the cup body be “hemispherically shaped” (claim 4) or “a partial

Art Unit: 3738

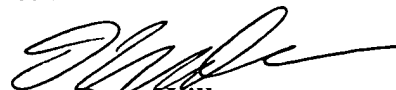
hemispherical shape” (claim 5) when the buttress 65 appears to be generally cylindrical (Figure 17)? If the greater and lesser extents are instead directed to the beveling of the partially spherical cup, as best seen in Figures 16, 18, and 19, then where is the support for the further limitations in claims 10, 11, and others? And if the language is directed to the same surface, then wouldn’t merely a hemispherical or partial hemispherical cup body having superior and posterior flanges *tilted* towards the distal direction be sufficient to meet the limitations at claim 1, lines 22-23? In claim 13, since the annular rim defines the cup periphery (claim 13, line 5) and the flanges extend from *adjacent* the annular rim (claim 13, lines 7-10), it is not understood how the concave surface *of the cup body wall* could extend “distally to a greater extent” (claim 13, line 24): if the buttress were part of the cup body, then the annular rim would be displaced *away* from the superior and posterior flanges. In claim 14, it is unclear whether “an inner, distal concave surface” (e.g., claim 14, line 2) is the same as or different from “a concave surface of the cup body wall” (e.g., claim 14, line 11). Similar errors exist in claim 23. In claim 14, lines 6 and 7, “the cup member” (both occurrences) lacks a proper antecedent basis. In claim 14, line 12, “the curved flange *member*” (emphasis added) lacks a proper antecedent basis. In claim 15, line 2, “the cup member” lacks a proper antecedent basis. Similar errors appear in claims 16, 17, and 19-22. Regarding claim 35, attention is directed to the remarks in the above rejection under 35 U.S.C. 112, first paragraph. In claim 47, line 5, “the cup member” lacks a proper antecedent basis; on lines 2-3, it is not seen how the “secondary concave surface” can be a part of the cup body and yet extend *from* the cup body. In claim 56, lines 4-5, how can the concave surface extend distally *from* the device when the concave surface is claimed as being *part of* the device itself? In claim 56, line 12, “the concave surface” is indefinite as to which of the concave

Art Unit: 3738

surfaces (lines 2 and 4) is being referenced; on line 14, "register" should be replaced by -- registers--. In claim 66, last line, "the fixation members" lacks a proper antecedent basis. In claim 74, line 2, "the diameter" lacks a proper antecedent basis.

The Applicant's remarks have been reviewed, but the art rejections have been withdrawn *without prejudice* because the examiner cannot ascertain the scope of claims which are imprecise and inconsistent with the original disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse  
Primary Examiner  
Art Unit 3738